AMENDED IN ASSEMBLY JUNE 30, 2003

AMENDED IN SENATE JUNE 3, 2003

AMENDED IN SENATE APRIL 30, 2003

AMENDED IN SENATE APRIL 21, 2003

AMENDED IN SENATE APRIL 10, 2003

## **SENATE BILL**

No. 857

## **Introduced by Senator Speier**

February 21, 2003

An act to amend Sections 14123.25 and 14172.5 of, to amend the heading of Article 1.3 (commencing with Section 14043) of Chapter 7 of Part 3 of Division 9 of, and to add Sections 14043.27, 14043.341, 14043.47, and 14170.10 to, the Welfare and Institutions Code, relating to Medi-Cal.

## LEGISLATIVE COUNSEL'S DIGEST

SB 857, as amended, Speier. Medi-Cal: error rate audit providers. Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Services, pursuant to which medical benefits are provided to public assistance recipients and certain other low-income persons.

This bill would declare the intent of the Legislature to enact legislation that would require the State Department of Health Services to conduct an error rate audit of the Medi-Cal program to determine the level of improper expenditures made to providers.

This bill would revise responsibilities of providers and applicants for participation as providers in the Medi-Cal program.

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This bill would also revise the standards that providers are required to meet in maintaining records of benefits provided by them under the Medi-Cal program.

The bill would impose restrictions upon Medi-Cal providers upon the dispensing or furnishing of certain drugs and devices, and for clinical laboratory tests or examinations.

Vote: majority. Appropriation: no. Fiscal committee: no—yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. It is the intent of the Legislature to enact legislation that would require the State Department of Health Services to conduct an error rate audit of the Medi-Cal program to determine the level of improper expenditures made to providers. SECTION 1. The heading of Article 1.3 (commencing with Section 14043) of Chapter 7 of Part 3 of Division 9 of the Welfare and Institutions Code is amended to read:

Article 1.3. Provider Enrollment, *Application, and Participation* 

SEC. 2. Section 14043.27 is added to the Welfare and Institutions Code, to read:

14043.27. (a) (1) An applicant that is not currently enrolled in the Medi-Cal program, a provider applying for continued enrollment, or a provider not currently enrolled at the location for which the application is submitted, shall submit a complete application package for enrollment, continuing enrollment, or enrollment at an additional location. The application package shall consist of a completed and signed application form, signed under penalty of perjury or notarized pursuant to Section 14043.25, a disclosure statement, a provider agreement, and all attachments or changes to the form, statement, or agreement.

- (2) Clinics licensed by the department pursuant to Section 1204 of the Health and Safety Code and certified by the department to participate in the Medi-Cal program shall be subject to this section.
- (3) Clinics licensed by the department pursuant to Chapter 2 (commencing with Section 1250) of Division 1 of the Health and

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Safety Code and certified by the department to participate in the Medi-Cal program shall not be subject to this section.

- (b) Within 30 days after receiving an application package, the department shall provide written notice that the application package has been received and, if applicable, that there is a moratorium on the enrollment of providers in the specific provider of service category or subgroup of the category to which the applicant or provider belongs, which moratorium shall bar further processing of the application package.
- (c) (1) Within 120 days after receiving an application package, the department shall give written notice to the applicant or provider that any of the following applies:
- (A) The application is denied for noncompliance with Section 14043.2 or 14043.36.
- (B) The application package is incomplete. The notice shall identify any additional information or documentation that is needed to complete the application package.
- (C) The department is exercising its authority under Section 14043.37, 14043.4, or 14043.7 and is conducting background checks, preenrollment inspections, or unannounced visits.
- (D) The applicant or provider is being granted provisional provider status for a period of 12 months, effective from the date on the notice.
- (2) For purposes of this section, "preenrollment period" includes the period of time during which an application package for enrollment, continued enrollment, or for the addition of a location is pending.
- (3) If the application package that was noticed as incomplete under subparagraph (B) of paragraph (1) is resubmitted with all requested information and documentation and received by the department within 35 days of the date on the notice, the department shall, within 60 days, send a notice that any of the following applies:
- (A) The applicant or provider is being granted provisional provider status for a period of 12 months, effective from the date on the approval notice.
- (B) The application is denied for any other reasons provided for in subparagraph (A) of paragraph (1).

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39 40 (C) The department is exercising its authority under Section 14043.37, 14043.4, or 14043.7 to conduct background checks, preenrollment inspections, or unannounced visits.

- (4) If the application package that was noticed as incomplete pursuant to subparagraph (B) of paragraph (1) is not resubmitted with all requested information and documentation and received by the department within 35 days of the date on the notice, the application shall be denied by operation of law. The applicant or provider may reapply by submitting a new application package that shall be reviewed de novo. However, if the failure to resubmit is by a provider applying for continued enrollment, the failure shall make the provider also subject to temporary suspension or immediate deactivation of all provider numbers used by the provider to obtain reimbursement from the Medi-Cal program. In addition, where the notice of an incomplete application package included a request for information or documentation related to grounds for denial under paragraph (1), the applicant or provider may not reapply for three years.
- (d) If the department exercises its authority under Section 14043.37, 14043.4, or 14043.7 to conduct background checks, preenrollment inspections, or unannounced visits, the applicant or provider shall receive notice, from the department, after the conclusion of the background check, preenrollment inspections, or unannounced visit that either the applicant or provider is granted provisional provider status for a period of 12 months or discrepancies or failure to meet program requirements, as prescribed by the director, have been found to exist during the preenrollment period. The notice shall identify the discrepancies or deficiencies, and whether remediation can be made or not, and if so, the time period within which remediation must be accomplished. Failure to remediate discrepancies deficiencies as prescribed by the director, or notification that remediation is not available, shall result in denial of the application by operation of law. The applicant or provider may reapply by submitting a new application package that shall be reviewed de novo. However, if the failure to remediate is by a provider applying for continued enrollment, the failure shall make the provider also subject to temporary suspension or immediate deactivation of all provider numbers used by the provider to obtain reimbursement from the Medi-Cal program. In addition, where the

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discrepancies or failure to meet program requirements, as prescribed by the director, included in the notice were related to grounds for denial under Section 14043.2 for failure to disclose, or the provision of false information; or under paragraph (1) of subdivision (c), the applicant or provider may not reapply for three years.

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(e) If provisional provider status is granted, a separate provider number shall be issued for each location for which an application has been approved. This provider number shall be used exclusively for the location for which it is issued. An applicant or provider who is a natural person, and licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, the Osteopathic Initiative Act, or the Chiropractic Initiative Act, shall be enrolled as either an individual provider or as a rendering provider in a provider group. Applicants or providers desiring to participate in the Medi-Cal program as a clinic shall be licensed as a clinic pursuant to Chapter 1 (commencing with Section 1200) of Division 2 of the Health and Safety Code or be exempt from clinic licensure under subdivisions (b) to (l), inclusive, or subdivisions (n) to (p), inclusive, of Section 1206 of the Health and Safety Code. An applicant or provider to which any of these clinic licensure exemptions applies may participate in the Medi-Cal program, provided the applicant or provider documents in its application package the legal justification for the exemption. Any applicant or provider that does not qualify as a licensed clinic or come within the exemptions from clinic licensure under Section 1206 of the Health and Safety Code may participate in Medi-Cal program within any other provider category for which the provider qualifies.

(f) (1) The department shall terminate provisional provider status of a provider, deactivate all provider numbers used by the provider to obtain reimbursement from the Medi-Cal program, and remove the provider from enrollment in the Medi-Cal program if, during the 12-month provisional status period or during announced or unannounced visits or any additional inspections or reviews conducted pursuant to this chapter or Chapter 8 (commencing with Section 14200) or the regulations adopted thereunder, the department discovers or determines the existence of any ground to deactivate the provider number or suspend the

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provider from the Medi-Cal program pursuant to this chapter or Chapter 8 (commencing with Section 14200) or the regulations adopted thereunder or if any of the following circumstances occur, with the exception of paragraph (3):

- (A) The applicant or provider, or persons with an ownership or control interest in the applicant or provider, persons who are directors, officers, or managing employees of an applicant or provider, have been convicted of any felony, or any misdemeanor involving fraud or abuse in any government program, or related to neglect or abuse of a patient in connection with the delivery of a health care item or service, or in connection with the interference with or obstruction of any investigation into health care related fraud or abuse, or have been found liable for fraud or abuse in any civil proceeding, or have entered into a settlement in lieu of conviction for fraud or abuse in any government program within 10 years of the date of the application package.
- (B) The applicant or provider is under investigation for fraud or abuse by the department or any state, local, or federal government law enforcement agency.
- (C) There is a discrepancy in the information provided to the department, or with the requirements to be enrolled, that cannot be corrected because the discrepancy occurred in the past.
- (D) The applicant or provider has provided material information that was false or misleading at the time it was provided.
- (E) The applicant or provider failed to have an established place of business for the location for which the application was submitted at the time of any onsite inspection, announced or unannounced visit, or any additional inspection or review conducted pursuant to this article or a statute or regulation governing the Medi-Cal program, unless the practice of the applicant or provider's profession is such that it requires the delivery of services at locations other than the business address and the department has approved the practice.
- (F) (i) The applicant or provider comes within the definition of a clinic but is not licensed as a clinic. The applicant or provider claims to be exempt from clinic licensure under Section 1206 or 1206.1 of the Health and Safety Code, but the applicant or provider is not a health care practitioner, or it is discovered that the applicant's or provider's service or business address is not

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owned or leased by the applicant or provider in sole practice for the practice of his or her profession within the scope of his or her license, or the service or business address is not owned or leased by a partnership or professional corporation to which the applicant or provider belongs along with one or more other licensed health care practitioners or is not operated as an office for the practice of their profession, within the scope of their license, or the applicant or provider fails to meet any other requirement necessary to qualify as exempt form clinic licensure.

- (ii) The applicant or provider performs clinical laboratory tests or examinations, but it or its personnel do not meet the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) and state clinical laboratory requirements, do not possess valid CLIA certificates and clinical laboratory registrations or licenses pursuant to Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code, or are not exempt from licensure under Section 1241 of the Business and Professions Code.
- (G) The applicant or provider, or if the applicant or provider is a clinic, group, partnership, corporation, or other association, any officer, director, or shareholder with a 10 percent or greater interest in that organization, commits two or more violations of the federal or state statutes or regulations governing the Medi-Cal program, and the violations demonstrate a pattern or practice of fraud, abuse, or provision of unnecessary or substandard medical services.
- (H) The applicant or provider commits any violation of a federal or state statute or regulation governing the Medi-Cal program or of a statute or regulation governing the applicant's or provider's profession or occupation and the violation represents a threat of immediate jeopardy or significant harm to any Medi-Cal beneficiary or to the public welfare.
- (I) The applicant or provider submits claims for payment that would subject a provider to suspension under Section 14043.61.
- (J) The applicant or provider submits claims for payment for services rendered at a location other than the location for which the provider number was issued, unless the practice of the applicant's or provider's profession or delivery of services is such that it requires the delivery of services at locations other than the business address and the department has approved the practice.

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 (K) The applicant or provider has not paid its fine, or has a debt due and owing, including overpayments, to any federal, state, or local government entity that relates to Medicare, medicaid, Medi-Cal, or any other federal or state health care program, and has not made satisfactory arrangements to fulfill the obligation or otherwise been excused by legal process from fulfilling the obligation.

- (2) The applicant or provider fails to possess the appropriate licenses, permits, certificates, or other necessary approvals that are needed to either practice his or her profession or occupation, or to provide the services, goods, merchandise, or supplies to Medi-Cal beneficiaries that the applicant or provider intends to provide at the location for which the application was submitted.
- (g) Termination of provisional provider status pursuant to subdivision (f) shall include removal of the provider from enrollment in the Medi-Cal program.
- (h) (1) If the provisional provider status is terminated and the provider number is deactivated or an application is denied pursuant to this section, the applicant or provider may not reapply for enrollment in the Medi-Cal program or for participation in any health care program administered by the department or its agents or contractors for a period of three years from the date the application is denied or the provisional status is terminated and the provider number deactivated, or from the date of the final decision following an appeal from termination except where paragraph (4) of subdivision (c) and paragraph (1) of subdivision (d) provide otherwise.
- (2) If the denial or termination is based upon a conviction for any offense or for any act included in paragraph (1) of subdivision (f), the applicant or provider may not reapply for enrollment or continued enrollment in the Medi-Cal program or for participation in any health care program administered by the department or its agents or contractors for a period of 10 years from the date the application is denied or the provisional status is terminated and the provider number deactivated or from the date of the final decision following an appeal from termination.
- (3) If the denial is based upon two or more convictions for any offense or for any two acts included in paragraph (1) of subdivision (f), the applicant or provider shall be permanently barred from enrollment in the Medi-Cal program or for

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participation in any health care program administered by the department or its agents or contractors.

- (4) The prohibition in paragraph (1) against reapplying for three years shall not apply if the denial of the application or termination of provisional provider status is based upon any of the following:
- (A) The grounds provided for in paragraph (2) of subdivision (f) if the disciplinary action is closed without any restrictions or conditions being taken against the applicant's or provider's license.
- (B) The grounds provided for in paragraph (4) of subdivision (f) if the investigation is closed without any adverse action.
- (C) The grounds provided for in paragraph (3) or (9) of subdivision (f).
- (i) (1) If the denial of an application or the termination of provisional provider status and deactivation of the provider number is based upon any of the grounds stated in subparagraph (A) of paragraph (3), or paragraph (1), (2), (4), (6), or (10) to (14), inclusive, of subdivision (f), any existing provider number assigned to the applicant or provider shall be deactivated and the applicant or provider shall be removed from enrollment in the Medi-Cal program by operation of law.
- (2) If the denial of the application or termination of provisional provider status is based upon the grounds stated in paragraph (2) of subdivision (b) and the disciplinary action is closed without any restrictions or conditions being taken against the applicant's or provider's license, or is based upon the grounds in paragraph (4) of subdivision (b) and the investigation is closed without any adverse action being taken, or is based upon the grounds in paragraph (3) or (9) of subdivision (f) and the applicant or provider obtains the appropriate license, permits, or approvals or is otherwise in compliance with clinical laboratory laws, the suspension taken pursuant to paragraph (1) of subdivision (h) shall be lifted and the previously deactivated provider number shall be reactivated, unless there are other grounds for taking these actions.
- (j) Claims that are submitted or caused to be submitted by a provider who has been suspended from the Medi-Cal program for any reason for services, goods, merchandise, or supplies rendered

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1 to Medi-Cal beneficiaries during the period of suspension shall2 not be paid.

- (k) An applicant or a provider whose application for enrollment, continued enrollment, or a new location or change in location has been denied, or whose provisional provider status has been terminated and provider numbers have been deactivated, pursuant to this section, may appeal in accordance with Section 14043.65.
- (1) If, at the end of the period for which provisional provider status was granted, all of the following conditions are met, the provisional status shall cease and the provider shall be enrolled in the Medi-Cal program without designation or a provisional provider:
- (1) The provider has demonstrated an appropriate volume of business.
- (2) The provisional provider status has not been terminated or the provider number has not been deactivated.
- (3) The application for enrollment or continued enrollment or for a new location has not been denied.
- (4) The provider continues to meet the standards for enrollment in the Medi-Cal program as set forth in Section 14043 et seq. of the Welfare and Institutions Code and Section 51000 et seq. of Title 22 of the California Code of Regulations.
  - (m) For the purposes of this section:
- (1) "A debt due and owing" means 60 days has passed since a notice or demand for repayment of an overpayment or other amount resulting from an audit or examination, or for a penalty assessment, or for any other amount due the department, was sent to the applicant or provider, regardless of whether the applicant or provider is an institutional provider or a noninstitutional provider and regardless of whether an appeal is pending. Any department recovered fine or debt due and owing, including overpayments, that are subsequently determined to have been erroneously collected shall be promptly refunded to the applicant or provider, together with interest paid in accordance with subdivision (e) of Section 14171 and Section 14172.5.
- (2) "Appropriate volume of business" means a volume that is consistent with the information provided in the application, and is of a quantity and type that would reasonably be expected based

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upon the size and type of business operated by the applicant or provider.

- (3) "Location" means a street or city address or a site or place within a street and city address, where the applicant or provider provides services, goods, supplies, or merchandise, directly or indirectly, to a Medi-Cal beneficiary.
- (4) "Not currently enrolled at the location for which the application is submitted" means either of the following:
- (A) The provider is changing his or her location and moving to a different location than that for which the provider number was originally issued.
- (B) The provider is adding an additional location to his or her practice.
- (n) (1) An applicant not currently enrolled in the Medi-Cal program, a provider applying for continued enrollment, or a provider not currently enrolled at the location for which an application is submitted, whose application package was received by the department prior to May 1, 2003, and for whom the application package has not been approved or denied by the department on the effective date of this section shall be granted provisional provider status on the effective date of this section, except those applicants or providers that the department has noticed, prior to January 1, 2004, that the department is exercising its authority under Section 14043.37, 14043.4, or 14043.7 to conduct background checks, preenrollment inspections, or unannounced visits. Application packages from applicants or providers who have been so noticed prior to January 1, 2004, shall be processed in accordance with subdivision (d).
- (2) Application packages from an applicant not currently enrolled in the Medi-Cal program, a provider applying for continued enrollment, or a provider not currently enrolled at the location for which an application is submitted, which have been received by the department after May 1, 2003, but prior to January 1, 2004, shall be processed in accordance with subdivisions (b), (c), and (d), except that such application packages will be deemed to have been received by the department on January 1, 2004.
- (o) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement this section by means of a provider bulletin or similar instruction, without taking further regulatory

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action. The department shall consult with interested parties and appropriate stakeholders in implementing this section, including all of the following:

- (1) Notifying provider representatives of the proposed action or change. The notice shall occur at least 10 business days prior to the meeting provided for in paragraph (2).
- (2) Scheduling at least one meeting to discuss the action or change.
  - (3) Allowing for written input regarding the action or change.
- (4) Providing at least 30 days' advance notice on the implementation and effective date of the action or change.
- SEC. 3. Section 14043.341 is added to the Welfare and 13 Institutions Code, to read:
  - 14043.341. (a) Each provider that dispenses or furnishes a controlled drug, a dangerous drug, or a dangerous device to a Medi-Cal beneficiary, or a drug or device requiring a written order or prescription for the drug or device to be covered under the Medi-Cal program shall maintain a record of the signature of the person receiving the drug or device. If that person is not the beneficiary for whom the drug or device was ordered or prescribed, the provider shall maintain a record of the recipient's relationship to that beneficiary; the printed name of the recipient; the date signed, and the prescription number or a description of the item or items dispensed. The signature shall either be that of the beneficiary for whom the order or prescription was written or the person who receives the item on the beneficiary's behalf. "Orders" that come within the definition in paragraph (8) of subdivision (b) do not need to come within the definition of "prescription or order" or used in paragraphs (4) to (7), inclusive, of subdivision (b) in order to meet the requirements of this section.
    - (b) For purposes of this section:
  - (1) "Controlled substance" shall mean any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code.
  - (2) "Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use, except veterinary drugs that are labeled as such, and includes the following:
  - (A) Any drug that bears the legend: "Caution: Federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

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(B) Any device that bears the statement: "Caution: Federal law restricts this device to sale by or on the order of a \_\_\_\_\_," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

- (C) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006 of the Business and Professions Code.
  - (3) "Drug or device" means:

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- (A) Drug as defined in Section 4023 of the Business and Professions Code.
- (B) Device as defined in Section 4025 of the Business and Professions Code.
- (C) Pharmaceuticals, medical equipment, medical supplies, orthotics and prosthetics, and other product-like supplies or equipment.
- (4) "Prescription" or "order" means an oral, written, or electronic transmission order that is both of the following:
- (A) Given individually for the person or persons for whom ordered that includes all of the following:
  - (i) The name or names and address of the patient or patients.
- (ii) The name and quantity of the drug or device prescribed and the directions for use.
  - (iii) The date of issue.
- (iv) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.
- (v) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients.
- (vi) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, or physician assistant who issues a drug order pursuant to Section 2746.51, 2836.1, or 3502.1 of the Business and Professions Code.
- 35 (B) Issued by a physician, dentist, optometrist, podiatrist, or 36 veterinarian or, if a drug order is issued pursuant to Section 37 2746.51, 2836.1, or 3502.1 of the Business and Professions Code,
- 38 by a certified nurse-midwife, nurse practitioner, or physician
- 39 assistant licensed in this state.

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 (5) "Electronic transmission prescription" includes both image and data prescriptions.

- (6) "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy or other appropriate provider from a licensed prescriber and that is reduced to writing and processed by the pharmacy or other appropriate provider in accordance with applicable provisions of the Business and Professions Code, including Section 4070.
- (7) "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy or other appropriate provider and which is reduced to writing and processed by the pharmacy or other appropriate provider in accordance with applicable provisions of the Business and Professions Code, including Section 4070. The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.
- (8) (A) An "order" also includes an entry on the chart or medical record of a patient registered in a hospital or a patient under emergency treatment in the hospital, by or on the order of a practitioner authorized by law to prescribe drugs, and it shall authorize the administration of the drug from hospital floor or ward stocks furnished by the hospital pharmacy or under licensure granted under Section 4056 of the Business and Professions Code:
- (B) An order meeting the requirements of subparagraph (A) shall be considered to be a prescription if the medication is to be furnished directly to the patient by the hospital pharmacy or another pharmacy furnishing prescribed drugs for hospital patients, so long as the chart or medical record of the patient contains all of the information required by Sections 4040 and 4070 of the Business and Professions Code and either the order is signed by the practitioner authorized by law to prescribe drugs, if he or she is present when the drugs are given, or, if he or she is not present when the drugs are given, the order is signed either by the attending physician responsible for the patient's care at the time the drugs are given to the patient or by the practitioner who ordered the drugs for the patient on the practitioner's next visit to the hospital.

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(c) Nothing in this section shall require a provider who dispenses or furnishes a complimentary sample of a dangerous drug to maintain the signature of the person receiving that drug.

- (d) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement this section by means of a provider bulletin or similar instruction, without taking further regulatory action. The department shall consult with interested parties and appropriate stakeholders in implementing this section, including all of the following:
- (1) Notifying provider representatives of the proposed action or change. The notice shall occur at least 10 business days prior to the meeting provided for in paragraph (2).
- (2) Scheduling at least one meeting to discuss the action or change.
  - (3) Allowing for written input regarding the action or change.
- (4) Providing at least 30 days' advance notice on the implementation and effective date of the action or change, except where another time period is required by law.
- SEC. 4. Section 14043.47 is added to the Welfare and Institutions Code, to read:
- 14043.47. (a) A physician doing business as a sole proprietorship, partnership, or professional medical corporation under Part 4 (commencing with Section 13400) of Division 3 of the Corporations Code enrolled as an individual provider or as a physician group provider shall be responsible for the overall operation of the business address for which it is enrolled.
- (b) A physician doing business as a sole proprietorship, partnership, or professional medical corporation under Part 4 (commencing with Section 13400) of Division 3 of the Corporations Code or a rendering physician provider in a group may not be enrolled unless there is a licensed physician for every four full-time nurse practitioners, for every three full-time nurse midwives, and for every two physician's assistants, or for any four of these individuals in any combination that does not exceed three nurse midwives or two physician's assistants, that are employed at the business address.
- (c) A physician doing business as a sole proprietorship, partnership, or Professional medical corporation under the Part 4 (commencing with Section 13400) of Division 3 of the

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1 Corporations Code or a rendering physician provider in a group,
2 may not be enrolled at more than three business addresses unless
3 there is a ratio of at least one physician providing supervision for
4 every three locations.

(d) A physician doing business as a sole proprietorship, partnership, or professional medical corporation under Part 4 (commencing with Section 13400) of Division 3 of the Corporations Code or a rendering physician provider in a group, who fails to comply with the requirements of this section is subject to temporary suspension from the Medi-Cal program and deactivation of all of his or her provider numbers.

SEC. 5. Section 14123.25 of the Welfare and Institutions Code is amended to read:

14123.25. (a) In lieu of, or in addition to, the imposition of any other sanction available to it, including the sanctions and penalties authorized under Section 14123.2 or 14171.6, and as the "single state agency" for California vested with authority to administer the Medi-Cal program, the department shall exercise the authority granted to it in Section 1002.2 of Title 42 of the Code of Federal Regulations, and may also impose the mandatory and permissive exclusions identified in Section 1128 of the federal Social Security Act (42 U.S.C. Sec. 1320a-7), and its implementing regulations, and impose civil penalties identified in Section 1128A of the federal Social Security Act (42 U.S.C. Sec. 1320a-7a), and its implementing regulations, against applicants and providers, as defined in Section 14043.1 or against billing agents, as defined in Section 14040.1. The department may also terminate, or refuse to enter into, a provider agreement authorized under Section 14043.2 with an applicant or provider, as defined in Section 14043.1, upon the grounds specified in Section 1866(b)(2) of the federal Social Security Act (42 U.S.C. Sec. 1395cc(b)(2). Notwithstanding Section 100171 of the Health and Safety Code or any other provision of law, any appeal by an applicant, provider, or billing agent of the imposition of a civil penalty, exclusion, or other sanction pursuant to this subdivision shall be in accordance with Section 14043.65, except that where the action is based upon conviction for any crime involving fraud or abuse of the Medi-Cal, medicaid, or Medicare programs, or exclusion by the federal government from the medicaid or Medicare programs the action shall be automatic and not subject to appeal or hearing.

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(b) In addition, the department may impose the intermediate sanctions identified in Section 1846 of the Social Security Act (42 U.S.C. Sec. 1395w-2), and its implementing regulations, against any provider that is a clinical laboratory, as defined in Section 1206 of the Business and Professions Code. The imposition and appeal of this intermediate sanction shall be in accordance with Article 8 (commencing with Section 1065) of Chapter 2 of Division 1 of Title 17 of the California Code of Regulations.

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- (c) (1) In addition, the department may issue a written warning notice of improper billing or improper cost computation to a provider via certified mail, return receipt requested whenever it is determined that the provider violated one or more material Medi-Cal program requirements, rules, regulations, or any section of this chapter or Chapter 8 (commencing with Section 14200) or any rule or regulation promulgated by the director pursuant to those chapters. The warning notice shall be in a format that apprises the provider of the item or service improperly billed, and if applicable, the deficiencies in the manner in which provider costs were computed. The warning notice may be issued in addition to any audit or any other action that the department is authorized to take. The failure of the department to exercise its discretion to issue the warning notice shall not be interpreted and shall not limit its authority to audit or take any action authorized by law. The warning notice shall provide the provider with the opportunity to contest the warning notice and explain to the department the correctness of the provider's bill or cost computation. If the department accepts the provider's explanation, in whole or in part, no further action related to the notice or part of the notice that the department accepts as correct shall be taken pursuant to this section.
- (2) Civil money penalties may be imposed in the following circumstances:
- (A) If a provider presents or causes to be presented a claim for payment by the Medi-Cal program that is:
- (i) Billed improperly, and is for a service or item about which the provider has received two or more notices of improper billing, the provider may, in addition to any other penalties that may be prescribed by law, be subject to a civil money penalty of one hundred dollars (\$100) per claim, or up to two times the amount improperly claimed for each item or service, whichever is greater.

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(ii) For a service or item for which the department solicits provider costs for use in calculating Medi-Cal reimbursement or in calculating and assigning Medi-Cal reimbursement rates, and the cost report relevant to the claim is improperly calculated, and the provider has received a warning notice of improper cost computation regarding substantially similar errors, the provider may, in addition to any other penalties that may be prescribed by law, be subject to a civil money penalty of one hundred dollars (\$100) per adjustment by the department to the costs submitted by the provider, or up to two times the amount improperly claimed for each item or service, whichever is greater.

- (B) If a provider presents or causes to be presented a claim for payment by the Medi-Cal program that is:
- (i) Billed improperly, and is for a service or item about which the provider has received three or more notices of improper billing, or has been assessed penalties under this section, the provider may, in addition to any other penalties that may be prescribed by law, be subject to a civil money penalty of one thousand dollars (\$1,000) per claim, or up to three times the amount improperly claimed for each item or service, whichever is greater.
- (ii) For a service or item for which the department solicits provider costs for use in calculating Medi-Cal reimbursement or in calculating and assigning Medi-Cal reimbursement rates, and the cost report relevant to the claim is improperly calculated, and the provider has received three or more warning notices of improper cost computation regarding substantially similar errors, or has been assessed penalties under this section, the provider may, in addition to any other penalties that may be prescribed by law, be subject to a civil money penalty of one thousand dollars (\$1,000) per adjustment by the department to the costs submitted by the provider, or three times the amount claimed for each item or service, whichever is greater.
- (3) Any provider subject to civil penalties under paragraph (2) shall have the same right as those rights of a provider under Section 14132.2.
- 36 SEC. 6. Section 14170.10 is added to the Welfare and 37 Institutions Code, to read:
- 38 14170.10. (a) No provider shall submit a claim to the 39 department or its fiscal intermediaries for the dispensing or 40 furnishing of a controlled drug, a dangerous drug, or a dangerous

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device, or a drug or device requiring a written order or prescription for the drug or device to be covered under the Medi-Cal program or for the performance of a clinical laboratory test or examination, except those for anatomical pathology examinations, unless the provider's records contain an order or prescription, signed by the person lawfully authorized by his or her practice act to prescribe or order the dispensing or furnishing of such drug or device, or the performance of a clinical laboratory test or examination, to or upon, a Medi-Cal beneficiary, except the following:

- (1) Providers who are physicians, clinics, hospitals, or other nonpharmacists and who are legally authorized to dispense or furnish drugs or devices directly to their patients, may in lieu of the requirements of this subdivision include a notation in their patients' medical charts reflecting they have dispensed or furnished the drug or device directly to the patient as authorized by the Business and Professions Code.
- (2) Anatomical pathology examinations may be ordered by physicians by notation within the patients medical record during inpatient or outpatient surgery. "Orders" that come within the definition in paragraph (9) of subdivision (b) do not need to come within the definition of "prescription or order" in subdivisions (5) to (8), inclusive, in order to meet the requirements of this section. Any claims made contrary to this section shall be subject to recovery as overpayments.
  - (b) For purposes of this section:

- (1) "Signed" shall include a signature that meets the conditions of the Electronic Signature in Global and National Commerce Act (15 U.S.C. Sec. 7001).
- (2) "Controlled substance" shall mean any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code.
- (3) "Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use, except veterinary drugs that are labeled as such, and which include the following:
- (A) Any drug that bears the legend: "Caution: Federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
- 39 (B) Any device that bears the statement: "Caution: Federal 40 law restricts this device to sale by or on the order of a \_\_\_\_\_," "Rx

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only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the 3 device.

- (C) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006 of the Business and Professions Code.
  - (4) "Drug or device" means:
- (A) Drug as defined in Section 4023 of the Business and Professions Code.
- (B) Device as defined in Section 4025 of the Business and Professions Code.
- (C) Pharmaceuticals, medical equipment, medical supplies, orthotics and prosthetics appliances, and other product-like supplies or equipment.
- (5) "Prescription" or "order" means an oral, written, or electronic transmission order that is both of the following:
- (A) Given individually for the person or persons for whom ordered that includes all of the following:
  - (i) The name or names and address of the patient or patients.
- (ii) The name and quantity of the drug or device prescribed and the directions for use.
  - (iii) The date of issue.
- (iv) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.
- (v) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients.
- (vi) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, or physician assistant who issues a drug order pursuant to Section 2746.51, 2836.1, or 3502.1 of the Business and Professions Code.
- (B) Issued by a physician, dentist, optometrist, podiatrist, or veterinarian or, if a drug order is issued pursuant to Section 2746.51, 2836.1, or 3502.1 of the Business and Professions Code, 36 by a certified nurse-midwife, nurse practitioner, or physician assistant licensed in this state.
- (6) "Electronic transmission prescription" includes both 38 image and data prescriptions.

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(7) "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy or other appropriate provider from a licensed prescriber and that is reduced to writing and processed by the pharmacy or other appropriate provider in accordance with applicable provisions of the Business and Professions Code, including Section 4070.

- (8) "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy or other appropriate provider and which is reduced to writing and processed by the pharmacy or other appropriate provider in accordance with applicable provisions of the Business and Professions Code, including Section 4070. The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.
- (9) (A) An "order" also includes an entry on the chart or medical record of a patient registered in a hospital or a patient under emergency treatment in the hospital, by or on the order of a practitioner authorized by law to prescribe drugs, it shall authorize the administration of the drug from hospital floor or ward stocks furnished by the hospital pharmacy or under licensure granted under Section 4056 of the Business and Professions Code,
- (B) An order meeting the requirements of subparagraph (A) shall be considered to be a prescription if the medication is to be furnished directly to the patient by the hospital pharmacy or another pharmacy furnishing prescribed drugs for hospital patients, so long as the chart or medical record of the patient contains all of the information required by Sections 4040 and 4070 of the Business and Professions Code and either the order is signed by the practitioner authorized by law to prescribe drugs, if he or she is present when the drugs are given, or, if he or she is not present when the drugs are given, the order is signed either by the attending physician responsible for the patient's care at the time the drugs are given to the patient or by the practitioner who ordered the drugs for the patient on the practitioner's next visit to the hospital.
- (10) "Clinical laboratory test or examination" means the detection, identification, measurement, evaluation, correlation, monitoring, and reporting of any particular analyte, entity, or

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 substance within a biological specimen for the purpose of obtaining scientific data that may be used as an aid to ascertain the presence, progress, and source of a disease or physiological condition in a human being, or used as an aid in the prevention, prognosis, monitoring, or treatment of a physiological or pathological condition in a human being, or for the performance of nondiagnostic tests for assessing the health of an individual.

- (c) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement this section by means of a provider bulletin or similar instruction, without taking further regulatory action. The department shall consult with interested parties and appropriate stakeholders in implementing the provisions of this section, including all of the following:
- (1) Notifying provider representatives of the proposed action or change. The notice shall occur at least 10 business days prior to the meeting provided for in paragraph (2).
- (2) Scheduling at least one meeting to discuss the action or change.
  - (3) Allowing for written input regarding the action or change.
- (4) Providing at least 30 days advance notice on the implementation and effective date of the action or change.
- SEC. 7. Section 14172.5 of the Welfare and Institutions Code is amended to read:
- 14172.5. (a) No later than 60 days after the completion of an audit or examination pursuant to Sections 10722 and 14170, the department shall issue the first statement of account status or demand for repayment.
- (b) Notwithstanding the provisions of Section 14172 or any other law, when it is established that an overpayment has been made to an institutional provider or a civil money penalty assessed pursuant to Section 14123.2 or 14123.25 is due from a provider, the department shall not begin liquidation of the overpayment until 60 days after issuance of the first statement of accountability or demand for repayment after issuance of the audit or examination report establishing the overpayment or the document establishing the penalty. The department shall pursue liquidation of the overpayment or penalty upon expiration of the 60-day period. Should it be found If the department finds, upon appeal, that no overpayment was made to, or no penalty is due from, the

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institutional provider, the department shall repay the amount collected, together with the payment of interest thereon, from the date occurring 60 days after issuance of the first statement of accountability or demand for repayment after issuance of the audit or examination report alleging the overpayment *or penalty*.

The provisions of this subdivision shall not be construed so as to affect the department's authority under other provisions of law for liquidation of overpayments to noninstitutional providers.

- (c) Liquidation of the overpayment or penalty may be by any of the following:
  - (1) Lump sum payment by the provider.

- (2) Offset against current payments due to the provider.
- (3) A repayment agreement executed between the provider and the department.
- (4) Any other method of recovery available to and deemed appropriate by the director.
- (d) An offset against current payments shall continue until one of the following occurs:
  - (1) The overpayment is recovered.
- (2) The department enters into an agreement with the provider for repayment of the overpayment.
- (3) The department determines, upon appeal, that there is no overpayment.
- (e) The provider shall pay interest on any unrecovered overpayments as provided by subdivision (h) of Section 14171. If recovery of a disallowed payment has been made by the department, a provider who prevails in an appeal of a disallowed payment shall be paid interest as provided by subdivision (g) of Section 14171.
- (f) Nothing in this section shall prohibit a provider from repaying all or a part of the disputed overpayment without prejudice to the provider's right to a hearing pursuant to subdivision (b) of Section 14171.
- (g) If on the basis of reliable evidence, the department has a valid basis for believing that, with respect to a provider, proceedings have been or will shortly be instituted in a state or federal court for purposes of determining whether the provider is insolvent or bankrupt under appropriate state or federal law, or that a provider is or will shortly be taking action which reasonably might seriously hinder or defeat the department's ability to collect

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- overpayments in the future, the department may immediately adjust any payments to the provider to a level necessary to insure that no overpayment to the provider is made.